IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES ATTACHED ON EXHIBIT A**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF BRIAN N. SCHWARTZ, M.D.

Plaintiffs hereby seek to exclude certain expert testimony proffered by Defendant Ethicon's ("Defendant") expert Brian N. Schwartz, M.D. ("Dr. Schwartz"). Ethicon has submitted Dr. Schwartz as a general causation expert in cases involving the TVT-O and the TVT-Secur.[1] In support of their Motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Schwartz is a Urologist. Although he does not have a subspecialty in Pelvic Floor Medicine and Reconstructive Surgery, Plaintiffs do not challenge his general qualifications.[2] Rather, Plaintiffs challenge Dr. Schwartz's opinions in relation to mesh design (pore size, mesh density, mechanical v. laser cut mesh), degradation, shrinkage or contracture, and the respective Instructions For Use (IFUs) for the TVT-O and the TVT-Secur, because each of these opinions exceed the bounds of his qualifications and are founded on insufficient facts and unreliable

[1] *See* Exhibit A for a list of all the TVT-O and TVT-S cases in which Dr. Schwartz has been identified as a general causation expert.

[2] Expert Report of Dr. Schwartz (TVT-O) at p. 1 (attached as Ex. B); Expert Report of Dr. Schwartz (TVT- Secur) at p. 1 (attached as Ex. C); *see also* Curriculum Vitae of Dr. Schwartz (attached as Ex. D.)

methodology.[3] Moreover, Plaintiffs move the Court to exclude Dr. Schwartz's opinions relating to the efficacy and safety of the TVT-Secur as they are unreliable and based on flawed methodology.

Dr. Schwartz's experience in the field of Urology does not render all of his opinions admissible. The admission of Dr. Schwartz's unfounded opinions, however, would be both contrary to law and present a serious risk of confusing the issues and misleading the jury in this case.[4] As this Court has recognized in this litigation:

> Just because an expert may be "qualified . . . by knowledge, skill, experience, training or education" does not necessarily mean that the opinion that the expert offers is "the product of reliable principles and methods" or that the expert "has reliably applied the principles and methods to the facts of the case."[5]

Accordingly, Dr. Schwartz should be prevented from offering testimony or opinions that exceed those permitted under *Daubert* and its progeny.

LEGAL STANDARD

The Court acts as gatekeeper to determine whether an expert's testimony is reliable and relevant.[6] This gatekeeping function applies not only to "scientific" testimony, but also to testimony based on "technical" and "other specialized" knowledge.[7] The proponent of expert opinion bears the burden of establishing its admissibility.[8] Where the proponent fails to establish all of the prerequisites of admissibility, the exclusion of expert testimony is within the court's

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[3] *See Phelan v. Synthes*, 35 Fed. Appx. 102, 105 (4th Cir. 2002) (the reasoning or methodology underlying testimony must be scientifically valid and able to be properly applied to the facts in issue.)

[4] *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)("[T]he court must recognize that due to the difficulty of evaluating their testimony, expert witnesses have the potential to 'be both powerful and quite misleading.') (citing *Daubert*, 509 U.S. at 596).

[5] *Cisson v. C.R. Bard, Inc.*, 2013 U.S. Dist. LEXIS 78061, * 42-43 (S.D.W.V. 2013); see also *Free v. Bondo-Mar-Hyde Corp.*, 25 F. App'x 170 (4th Cir. 2002) (affirming the exclusion of testimony because highly credentialed expert nevertheless lacked knowledge of specific matters essential to subject of his opinion).

[6] *Daubert*, 509 U.S. at 598 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999); Fed. R. Evid. 702.

[7] *Kumho Tire Co., Ltd.*, 526 U.S. *at* 141.

[8] *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

sound discretion.[9] The admissibility of expert opinion testimony is governed by the Federal Rules of Evidence.[10] In a federal court sitting in diversity jurisdiction, the admissibility of expert testimony is a question of and controlled by federal law.[11] In multidistrict litigation, the law of the transferee circuit governs questions of federal law.[12]

The proponent of expert testimony must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible."[13] Expert testimony is admissible if the expert is proven to be qualified and said testimony (1) "will help the trier of fact to understand the evidence or to determine a fact in issue," (2) is "based upon sufficient facts or data," (3) is "the product of reliable principles and methods" and (4) has been reliably applied "to the facts of the case."[14] An expert's opinion is inadmissible unless the expert is qualified by virtue of knowledge, skill, experience, training or education," which is sufficiently related to the particular subjects at issue in the case.[15] In the context of Rule 702, knowledge "connotes more than subjective belief or unsupported speculation."[16] Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the *matters upon which she will opine are clearly within her area of expertise*."[17] One of the fundamental prerequisites

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[9] *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142 (1997).
[10] *Daubert*, 509 U.S. at 587.
[11] *See, e.g., Bryte v. Am. Household, Inc.*, 429 F.3d 469, 476 (4th Cir. 2005) (*quoting Scott v. Sears, Roebuck & Co.*, 789 F.2d 1052, 1054 (4th Cir. 1986)); *Fraley v. Stoddard, D.P.M.*, 73 F. Supp. 2d 642, 646 (S.D. W.Va. 1999).
[12] *See, e.g., In re Temporomandibular Joint Implants Prod. Liab. Litig.*, 97 F.3d 1050, 1155 (8th Cir. 1996) (*citation omitted*), *aff'd*, 490 U.S. 122 (1989)); *In re Stucco Litig.*, 364 F. Supp. 2d 539, 540 (E.D.N.C. 2005) ("[i]n the context of this multidistrict case, the court must apply the law of the Fourth Circuit when analyzing questions of federal law").
[13] *Maryland Cas. Co. v. Therm–O–Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998).
[14] Fed.R.Evid. 702.
[15] Fed. R. Evid. 702; *see, e.g., Cooper v. Lab. Corp. of Am. Holdings, Inc.*, 150 F.3d 376, 380 (4th Cir. 1998); *Bombardiere v. Schlumberger Tech. Corp.*, 934 F. Supp. 2d 843, 846 (N.D. W. Va. 2013).
[16] *Daubert*, 509 U.S. at 590.
[17] *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007) (emphasis added).

of the admission of an expert's opinion is that it be related to that expert's specialized knowledge.[18]

ARGUMENT

I. THIS COURT SHOULD EXCLUDE DR. SCHWARTZ'S OPINIONS RELATED TO THE MATERIAL PROPERTIES OF TVT-O AND TVT-SECUR SYNTHETIC MESH

Even though Dr. Schwartz does not have any experience in material science or designing a mesh product, has never analyzed, tested, or studied polypropylene mesh, and has never looked at mesh under a microscope, he offers opinions regarding the material properties of polypropylene used in the TVT-O and the TVT-Secur.[19] Specifically, he opines that: he has found no clinically significant difference between mechanically-cut mesh and laser-cut mesh;[20] that laser cut mesh is "state of the art";[21] that he has not seen fraying, roping, or curling in his clinical practice;[22] and the pore size and weight of the mesh used in the TVT-O and TVT-Secur are optimal.[23]

Dr. Schwartz testified he is a "materials expert" because he has implanted mesh products for decades though he readily admitted that he had not studied polypropylene or mesh in the same way that a polymer scientist might.[24] Dr. Schwartz has never designed mesh and has no training as a medical device engineer.[25] Dr. Schwartz is not a pathologist.[26] Dr. Schwartz has

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[18] *See, e.g., U.S. v. Johnson*, 54 F.3d 1150, 1157 (4th Cir. 1995).
[19] See Ex. E at 75:16-79:9 (TVT-O deposition)
[20] Ex. B at 28; Ex. C at 27.
[21] Ex. B at 28; Ex. C at 28.
[22] Ex. B at 28.
[23] Ex. B at 30; Ex. C at 30.
[24] Ex. E at 76:13-77:1.
[25] Ex. E at 67:8-12.
[26] Ex. E at 76:13-77:11

only viewed mesh grossly upon explant and has not analyzed explanted mesh under the microscope.[27]

In relation to mechanical-cut vs. laser-cut mesh, Dr. Schwartz offers the opinions that laser cut mesh is "state of the art" and that "I have not found there to be a clinically significant difference in the way the mesh itself performs."[28] Dr. Schwartz bases these opinions on his personal experience.[29] Yet, Dr. Schwartz does not keep a log or registry of his patients who have been implanted with mechanical-cut versus laser-cut mesh and has no method of tracking and evaluating his patients' outcomes. Dr. Schwartz has never studied the clinical differences between the mesh cut mechanically versus with a laser. Dr. Schwartz states that literature supports mechanically-cut mesh, but acknowledges that medical literature does not differentiate between laser-cut and mechanically-cut mesh.[30] Dr. Schwartz fails to employ any methodology (much less a reliable one) in reaching this opinion.

Dr. Schwartz also fails to employ appropriate methodology in reaching his opinion that mesh does not fray, rope, or curl as he bases the opinion on his clinical practice. As noted below, it is not enough for a clinician to base his "expert" opinion on his clinical experience. The opinion must be a product of reliable principles and methods which in this case, it is not. When asked what he had done in his clinical practice to assure himself that mesh was not "fraying, roping or curling" in his patients, he testified: that he had not performed ultrasounds in patients with products in place; had examined removed mesh grossly but had not documented

[27] Ex. E at 76:13-14; 77:7-11.
[28] Ex. B at 28.
[29] Ex. E at 65:1-23.
[30] Ex. E at 68:8-69:6.

those findings in any way; and had not performed a literature search on fraying, roping, or curling, but had relied on literature provided by Ethicon counsel.[31]

Dr. Schwartz, for both the TVT-O and TVT-Secur, opines that "the pore size and weight of the mesh used in the TVT-O [and TVT-Secur] is optimal."[32] Dr. Schwartz has neither performed researched, published literature, or taught courses on the issue of pore size or mesh density; the sole basis of his opinion is reading materials provided to him by Ethicon.[33] Dr. Schwartz's qualifications as a physician, even a physician specializing in urology, are not sufficient to allow him to testify regarding pore size and mesh density.

Dr. Schwartz's qualifications are insufficient to allow him to render expert opinions regarding the design of a pelvic device. Likewise, Dr. Schwartz's methodology is unreliable. Dr. Schwartz's opinions relative to – mechanical-cut v. laser-cut mesh; fraying, curling and roping; pore size and density – amount to nothing more than conjecture, and the law is clear that such "unsupported speculation" is not only insufficient, but precisely what *Daubert* aims to prevent.[34]

In *Tyree v. Boston Scientific Corp.*,[35] this Court excluded opinions by Dr. Jerry G. Blaivas, one of the plaintiff's experts, relating to the design of pelvic mesh products. The Court ruled:

> Dr. Blaivas's experience removing SUI devices and observing complications during the removal process does not alone render him qualified to opine as to design. Dr. Blaivas worked in developing the autologous rectus fascial sling operation. However, this experience in developing procedures does not make him

[31] Ex. E at 65:24-67:6.
[32] Ex. B at 30; Ex. C at 30.
[33] Ex. E at 83:7-84:22
[34] *Brown v. Auto-Owners Ins. Co.*, No. 96-2613, 1997 U.S. App. LEXIS 23559, *3 (4th Cir., Sept. 8, 1997)(the expert's testimony must be grounded in the methods and procedures of science and not subjective belief or unsupported speculation); *see also Bryte v. Am. Household, Inc.*, 429 F.3d 469, 477 (4th Cir. 2005).
[35] 2014 WL 5320566 (S.D.W. Va. 2014).

> an expert in the design of a medical device. (See Blaivas Report [Docket 239–1], at 1–2). As a result, Dr. Blaivas lacks the "knowledge, skill, experience, training, or education" as to product design that Federal Rule of Evidence 702 requires. Fed.R.Evid. 702.[36]

In *Huskey v. Ethicon*,[37] this Court excluded the testimony of Dr. Michael Greenburg, a board certified toxicologist, relating to the biocompatibility and mesh degradation. Dr. Greenberg had never testified about those subjects and admitted he was not a biomaterials expert.[38]

Dr. Schwartz's qualifications and experience do not rise to the same level as physicians that this Court has found were qualified to testify about design and biocompatibility issues. In *Wise v. C.R. Bard, Inc.*,[39] this Court rejected the plaintiff's challenge to Dr. Marshall Austin, who specialized in gynecologic surgical pathology and cytopathology and examined 15-20 specimens per month, including specimens involving pelvic mesh products. This Court rejected the challenge to his qualifications and ruled:

> In addition to his extensive background in the field of gynecological pathology, where his experience ranges from publishing research to giving academic lectures, Dr. Austin has examined hundreds of vaginal mesh explants over the past ten years. (See generally Austin Report [Docket 203–1]). I find his qualifications sufficient to testify about the biocompatibility of mesh.[40]

Even though the Court determined that Dr. Austin was qualified to testify about biocompatibility, the Court excluded Dr. Austin's opinions on design and concluded:

> I agree with the plaintiffs that these opinions about the Avaulta's overall design go beyond Dr. Austin's expertise. While he has studied and observed the interaction between tissue and mesh products such that he can opine about biocompatibility, he has no demonstrated experience in designing or evaluating transvaginal products.[41]

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[36] *Tyree*, 2104 WL 5320566 at *47.
[37] 2014 WL 3362264 (S.D.W. Va. 2014).
[38] *Huskey*, 2014 WL 3362264 at *26-27.
[39] 2015 WL. 570070 (S.D.W. Va. 2015).
[40] *Wise*, 2015 WL. 570070 at *3.
[41] *Id.* at *4.

On the other hand, the Court concluded that Dr. Donald R. Ostergard, one of the plaintiff's experts in *Tyree*, was qualified to testify about design issues due to his experience, including experience in the development of pelvic mesh products. The Court ruled:

> After reviewing Dr. Ostergard's curriculum vitae, I conclude that Dr. Ostergard is qualified to provide opinion testimony on the design of polypropylene slings. He has performed countless pelvic reconstruction surgeries, instructed others on the performance of these surgeries, participated in the development of pelvic mesh devices, and authored several peer-reviewed articles on the safety and efficacy of polypropylene mesh products.[42]

The basis of Dr. Schwartz's opinions regarding the design of the TVT-O and TVT-Secur is based primarily on his clinical experience. In light of his admitted lack of education, experience, training and knowledge, Dr. Schwartz is not qualified and should not be allowed to testify regarding the design of the TVT-O and the TVT-Secur, specifically the topics of mechanical-cut v. laser-cut mesh; fraying, curling and roping; pore size and density. These opinions exceed the bounds of his qualifications and should be excluded.

II. THIS COURT SHOULD EXCLUDE DR. SCHWARTZ'S OPINIONS RELATED TO DEGRADATION

In his reports, Dr. Schwartz states that he disagrees with Plaintiffs' experts that mesh degrades and that he "has not observed any clinically significant degradation of the TVT-O [or TVT-Secur] in my practice nor have I heard reports from colleagues."[43] The pertinent question to this analysis is not whether or not Dr. Schwartz is right or wrong. Plaintiffs do not need to challenge these opinions based on their accuracy.[44] The fatal flaw in Dr. Schwartz's opinions is his methodology.

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[42] *Tyree*, 2104 WL 5320566 at *36; *see also Wise v. C.R. Bard, Inc.*, 2015 WL 521202, *7 (S.D.W. Va. 2015) (finding Dr. Ostergard was qualified to testify about design issues).
[43] Ex. B at 30; Ex. C at 28-29.
[44] *See Westberry*, 178 F.3d at 261(the focus is on the principles and methodology, not the conclusions reached. Further, the court need not determine if expert testimony is irrefutable or necessarily correct.)

Dr. Schwartz bases his opinion that mesh does not degrade on the following: 1) his clinical experience (i.e., he opines if mesh degraded, surgeons would see it in their clinical practice and since he has not seen what he deems as evidence in his clinical practice, mesh must not degrade); 2) when he explants mesh and looks at it grossly he sees no evidence of degradation;[45] and 3) literature reporting the outcomes of clinical trials testing the efficacy of the products do not report degradation.[46] Dr. Schwartz has not reviewed Ethicon documents that discuss degradation.[47] In his report, Dr. Schwartz attempts to bolster his opinions by critiquing Clave (2010)[48] suggesting that the study (which concludes that mesh degrades) is flawed or inconclusive because the authors did not explain how the analyzed samples were selected. Dr. Schwartz did not perform any specific research or seek out any other information regarding degradation.

Under *Daubert,* a literature review must be performed appropriately in order to be part of a reliable methodology; as part of this, the Court must find more than an expert's own "hypothesis and speculation."[49] Dr. Schwartz relies on clinical studies only, failing to review and consider extensive literature that studies the changes that occur in mesh while in vivo. He disregards Clavé and other literature contrary to his opinion without adequate explanation. He relies primarily on his personal experience, having never examined mesh microscopically. He has never conducted testing on mesh that he has removed to determine whether the mesh had degraded. Dr. Schwartz does not have the necessary expertise to render an opinion regarding

[45] Ex. E at 77:2-20.
[46] Ex. E at 77:12-20; 80:23-81:16.
[47] Ex. E at 78:22-79:9.
[48] Clavé A, Yahi H, Hammou JC, et al. Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants. *Int Urogynecol J,* 2010; 21:261-270.
[49] *Doe v. Ortho-Clinical Diagnostics, Inc.,* 440 F. Supp. 2d 465, 473-74 (M.D.N.C. 2006) (excluding expert testimony based on a literature review, stating that it must be based on more than "hypothesis and speculation," that the review was "disconnected" and not derived by the scientific method.)

degradation and has admittedly not applied any scientific methodology in reaching his conclusions. His opinions regarding degradation should be excluded.[50]

III. THIS COURT SHOULD EXCLUDE DR. SCHWARTZ'S OPINIONS RELATED SHRINAKAGE OR CONTRACTURE

In his report, Dr. Schwartz states that "I have not seen clinically significant contraction in the TVT-O [and TVT-Secur] mesh slings that I have used."[51] A doctor's personal experience claiming to have not seen evidence of mesh shrinkage cannot serve as a reliable scientific basis for rendering an expert opinion in Federal court that, *i.e.*, tissue and the mesh within do not contract or "shrink" after implantation.

When asked what he had done to evaluate whether mesh shrinks, he replied, "clinical examination" but admitted he had made no effort during the examinations of his patients to evaluate any differences in the surface area of the mesh.[52] He did not perform vaginal ultrasounds.[53] He testified he had reviewed some studies that discussed shrinkage, but that he relied on literature that "attests to effectiveness" in reaching his conclusion that shrinkage of mesh does not have clinical significance.[54] Dr. Schwartz was unable to name any articles that disagreed with his position.[55] Dr. Schwartz has not performed any studies to measure contracture of mesh.[56]

Dr. Schwartz's opinions regarding shrinkage should be excluded not only because he lacks the necessary qualifications but because of his complete failure to consider or account for

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[50] *Oglesby v. GMC*, 190 F.3d 244, 250 (4th Cir. 1999) ("A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.")
[51] Ex. B at 28; Ex. C at 28.
[52] Ex. E at 69:7-70:13.
[53] Ex. E at 66:14-17.
[54] Ex. E at 72:12-24.
[55] Ex. E at 73:10-74:23
[56] Ex. E at 75:11-15.

any contrary scientific authority. Moreover, *Daubert* provides guidance regarding the factors that should be applied:

> *Daubert* mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

In re C.R. Bard, Inc. Pelvic Repair System Prods. Liab. Litig., 948 F.Supp.2d 589, 602 (S.D.W.Va.2013) (*citing Daubert v. Merrell Dow Pharm.*, 509 U.S. 579 (1993)).

Dr. Schwartz's opinions purporting to deny that mesh shrinkage has any clinical effect fail under every one of these reliability factors. His opinions are directly contrary to numerous published, peer-reviewed articles, which establish beyond reasonable scientific dispute the general acceptance of the phenomenon of *in vivo* mesh shrinkage. Dr. Schwartz absolutely fails to mention or account for the numerous peer-reviewed and published articles that establish mesh shrinkage. As this Court recognized in *Tyree v. Boston Scientific Corp.*, Case 2:12-cv-08633, Dkt. No. 444, p. 118 (*Daubert* Order):

> An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape." *In re Rezulin Products Liab. Litig.*, 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (quotations omitted). "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Id.*

See also, In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig., 2014 WL 2921648, *9 (E.D.Pa.2014) (expert's "opinion relies upon a selected subset of evidence without sufficient analysis of contrary evidence – a significant methodological weakness…. The fact that her conclusions are drawn from trends she observed in a self-selected subset of supportive studies,

not the totality of the epidemiological evidence, further underscores her problematic methodology.").

The overwhelming weight of the published scientific literature establishes mesh shrinkage as a generally accepted scientific phenomenon. Just a few of the many peer-reviewed scientific and medical articles addressing the phenomenon of mesh shrinkage, which Dr. Fleischman completely disregards, are discussed briefly below:

1. Feiner, B. and C. Maher (2010). "*Vaginal mesh contraction: definition, clinical presentation, and management.*" Obstet Gynecol 115 (2 Pt 1): 325-330. ("Vaginal mesh contraction is a serious complication after prolapse repair with armed polypropylene mesh that is associated with substantial morbidity, frequently requiring surgical intervention.") (Ex. F).

2. Garcia-Urena, et al. (2007). "*Differences in polypropylene shrinkage depending on mesh position in an experimental study.*" The American Journal of Surgery 193: 538–542 ("We conclude that PP meshes undergo an important degree of shrinkage that occurs during the scarring and remodeling process.") (Ex. G).

3. Hansen, N. L., A. Barabasch, et al. (2013). "*First In-Human Magnetic Resonance Visualization of Surgical Mesh Implants for Inguinal Hernia Treatment.*" Invest Radiol. 48 (11): 770-778. ("The amount of tissue reaction [to mesh implants] depends on the inserted material and its pore size. Scar tissue formation can lead to contraction, shrinkage, and deformation of mesh implants. This implant deformation is commonly blamed for severe mesh-related complications such as migration and penetration into abdominal organs, fistula formation, and, most of all, chronic pain, which can occur in up to 30% of cases.") (Ex. H).

4. Klinge, U., B. Klosterhalfen, et al. (1998). "*Shrinking of polypropylene mesh in vivo: an experimental study in dogs.*" Eur J Surg 164(12): 965-969. ("Meshes that contain a lot of polypropylene shrink to about 30%–50% of their original size after 4 weeks, requiring an overlap of at least 3 cm if implanted subfascially. Reduction in the polypropylene content decreases both the inflammatory response and the shrinkage. Meshes with big pores are less likely to fold and improve compatibility." Observing 34% shrinkage of hernia mesh) (Ex. I).

5. Klinge, U., B. Klosterhalfen, et al. (1999). "*Foreign body reaction to meshes used for the repair of abdominal wall hernias.*" Eur J Surg 165(7): 665-673. ("In accordance with the published data,…polyester and polypropylene lead to a pronounced chronic inflammation (2,3, 9) and a strong interlinking formation of connective tissue through the mesh-pores. This embedding connective tissue forms a rigid scar plate and is responsible for mesh shrinkage of 20% in length or 40% in mesh area, respectively, compared with the original mesh in its native, non-implanted condition.") (Ex. J).

6. Klosterhalfen, B., K. Junge, et al. (2005). "*The lightweight and large porous mesh concept for hernia repair*." Expert Rev Med Devices 2(1): 103-117. ("[T]here is now broad acceptance that shrinkage is a common phenomenon after mesh implantation…. It is not the mesh that shrinks, but the surface reduction is due to a simple retraction of the fibrotic scar tissues around the mesh. Retraction of the scar is a physiologic reaction of maturing scar started by a constant water loss and a subsequent surface-area decrease to an average 60% of the former wound region.") (Ex. K).

7. Letouzey V., et al. (2009). "*Ultrasound evaluation of polypropylene mesh contraction at long term after vaginal surgery for cystocele repair*." Int Urogynecol J 20(Suppl 2): S205. ("3D Ultrasound reconstruction [showed] a mean contraction of 30%, 65%, 85%, at a mean follow up of 3 years (n=12), 6 years (n=16), 8 years (n=12) respectively. Furthermore, we observed a linear evolution of the contraction rate between 18 months and 9 years after the mesh implantation.") (Ex. L).

8. Svabik K, et al. (2009) "*Vaginal mesh shrinking – ultrasound assessment and quantification.*" Int Urogynecol J 20:S166 ("We know from experimental studies that the large mesh area caused strong inflammatory reaction which results in integration of the mesh to the tissue and is associated with retraction-shrinkage of the mesh…. The shrinking of the polypropylene mesh is described from 30% to 50% in some animal studies…. The Gynemesh [product involved in the study] shrinks one fifths of its length. The folding has a major impact on the final length of the large meshes (36%) and it seems to be irreversible…. The significant increase in vaginal wall thickness after vaginal surgery is apparently caused by the mesh and not by the surgery.") (Ex. M).

9. Tunn, R., A. Picot, et al. (2007). "*Sonomorphological evaluation of polypropylene mesh implants after vaginal mesh repair in women with cystocele or rectocele*." Ultrasound Obstet Gynecol 29(4): 449-452 (observing and reporting significant mesh shrinkage in pelvic organ prolapse mesh with ultrasound) (Ex. N).

Dr. Schwartz's complete and inexplicable failure to consider or account for any of this abundant literature renders his opinions regarding shrinkage or contracture wholly unreliable, accordingly, Dr. Schwartz's opinion that tissue/mesh shrinkage has no clinical implications should be excluded.

IV. THE COURT SHOULD EXCLUDE DR. SCHWARTZ'S TESTIMONY ON THE TVT'S INSTRUCTIONS FOR USE ("IFU")

In his reports, Dr. Schwartz opines in regard to both the TVT-O and TVT-Secur IFUs as follows:

> The IFU also includes a list of potential Adverse Reactions noting that punctures or lacerations of blood vessels, nerves, bladder, urethral, or bowel may occur, that transitory local irritation at the wound site and a transitory foreign body response may occur, which could result in extrusion, erosion, fistula formation, or inflammation, that infection may occur, and that over-correction or over tensioning may cause temporary or permanent lower urinary tract obstruction. In my opinion, these warnings are adequate. There is no need for Ethicon to warn surgeons about risks inherent in any pelvic floor surgery such as infection, inflammation, bleeding, scarring, bladder damage, bowel damage, nerve damage, ureteral damage, pain, pelvic pain, dyspareunia, groin pain, bladder or bowel dysfunction, fistula, anesthetic risks, wound complications such as erosion, wound dehiscence, exposure, wound herniation, hematoma, need for reoperation, failure of the operation, and anesthetic risks. Nor is there any need to warn surgeons about the severity, frequency, or permanency of any of these complications. Surgeons know from their education, training, and experience that complications can be mild, moderate, or severe, permanent or temporary, and data on complication frequency is available in peer-reviewed literature, which surgeons have an obligation to review. In my opinion, the warnings and instructions provided in the TVT-O IFU are adequate.[57]

Dr. Schwartz has not written an IFU.[58] He has not consulted with a medical device manufacturer on the drafting of an IFU. His entire exposure to what is required in an IFU was skimming the FDA's Device Labeling Guide, a document he had never seen outside of litigation.[59] Dr. Schwartz's opinions regarding what he would consider to be an adequate warning are based on his personal opinion.

Dr. Schwartz is unqualified to testify on the specific issue of product warnings. He is neither familiar with the standards applicable to medical device IFUs nor the process by which IFUs are developed and approved.[60] He does not rely on any standards in rendering his opinions regarding the TVT-O and TVT-Secur IFUs. Rather, he relies solely on his own personal opinion and experience. The United States Supreme Court, the Fourth Circuit and this Court have all expressly held that an opinion based on nothing more than the *ipse dixit* of the expert is

[57] Ex. B at 31-32; Ex. C at 32.
[58] Ex. O at 58:8-20.
[59] Ex. E at 135:10-136:6.
[60] *In re: C. R. Bard, Inc. (Cisson)*, 948 F. Supp. 2d 589, 611 (S.D.W.Va. 2013).

inadmissible.[61] This Court has previously rejected this "I have not seen any risks in my practice that were not in the defendant's product instructions, so therefore the instructions are adequate":

> Author and astronomer, Carl Sagan, popularized the aphorism, "Absence of evidence is not evidence of absence." Carl Sagan, *The Demon-Haunted World: Science as a Candle in the Dark* 213 (1996). Sagan's aphorism illustrates the logical fallacy that a premise is not necessarily true merely because it has yet to be proven false. Instead, there is often insufficient investigation and information to come to a conclusive determination. Sagan's musings are relevant here because for the first time during these MDLs, the plaintiffs have challenged the defendant's attempt to offer experts seeking to opine on the adequacy of product warnings. In the past, I allowed a doctor to testify that the DFU was inadequate because it failed to warn against risks the doctor observed in his or her own practice. In contrast, now I must determine whether the same kind of doctor is instead qualified to offer his expert opinion that the warnings were in fact adequate. There is a clear distinction. The plaintiffs' experts observed certain risks and complications in their practice and then sought to opine that those risks should have been included in the product warnings. In the present case, BSC's experts have observed certain risks and complications in their practice, which are warned of in the DFU, and therefore deduce that there are no other possible risks or complications that should have been included. The plaintiffs' experts address a discrete risk which they have personally observed, while BSC's experts' opinions attempt to encompass all possible risks, none of which they have personally observed. Accordingly, I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks he has observed in his own practice.

Tyree v. Boston Scientific Corp., Case 2:12-cv-08633, Dkt. No. 444, p. 118 (*Daubert* Order). A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid

[61] *See, e.g., General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) (holding that "nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* [an assertion made but not proved] of the expert"); *Cooper*, 259 F.3d at 202-03 (same); *Bourne v. E.I. Dupont de Nemours & Co., Inc.*, 189 F. Supp. 2d 482, 499 (S.D.W. Va. 2002) (same); *see also Hoffman v. Monsanto Co.,* No. 2:05-CV- 00418, 2007 WL 2984692, *4 (S.D.W. Va. Oct. 11, 2007) (excluding an opinion that was based on "simply a subjective, conclusory approach that cannot reasonably be assessed for reliability") (*quoting* Fed. R. Evid. 702, advisory committee's note (2000)).

methods."[62] Dr. Schwartz's opinions concerning the adequacy of the TVT-O and TVT-Secur IFUs are unreliable and should be excluded.

V. THE COURT SHOULD EXCLUDE DR. SCHWARTZ'S OPINIONS REGARDING PROFESSIONAL EDUCATION

In both his TVT-O and TVT-Secur reports, Dr. Schwartz opines about his experience with Ethicon's professional education program.[63] When asked if he held an opinion regarding Ethicon's professional education program, Dr. Schwartz testified that he did not hold an opinion regarding the effectiveness of the program in relation to the products but only that he had had a positive experience.[64] Dr. Schwartz's personal experience with Ethicon's training program is not the proper subject matter of expert testimony and should be excluded.

V. THE COURT SHOULD EXCLUDE DR. SCHWARTZ'S OPINIONS REGARDING THE SAFETY AND EFFICACY OF THE TVT-SECUR

In his report, Dr. Schwartz opines that the TVT-Secur is safe and effective.[65] The TVT-Secur is not a full-length mid-urethral sling, but rather a "mini-sling" that only requires one incision.[66] Rather than using trocars, only use inserters are used to implant the TVT-Secur. In support of his opinion that the TVT-Secur was safe and effiective,[67] Dr. Schwartz cites a 2015 Cochrane Review entitled, "Mid-urethral sling operations for stress urinary incontinence in women."[68] Dr. Schwartz testified that he considered the 2015 Cochrane review to be good qualify scientific, Level 1 evidence and that he had confidence in the reliability of Cochrane

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[62] *Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4th Cir.1999).
[63] Ex. B at 33; Ex. C at 33.
[64] Ex. O at 58:24-59:9.
[65] Ex. C at 19-24.
[66] Ex. C at 16-18.
[67] The TVT-Secur is no longer on the market. See Ex. C at 18.
[68] Ex. C at 21; Ford AA, et al., Mid-urethral sling operations for stress urinary incontinence in women. Cochrane Database of Systematic Reviews 2015, Issue 7. Art. No.: CD006375. DOI: 10.1002/14651858.CD006375.pub3. (Ex. U).

reviews when evaluating a mid-urethral slings.[69] He testified that the results of Ford 2015 Cochrane review could be extrapolated to the TVT-Secur and support a conclusion that the device is safe and effective.

In fact, the Cochrane review Dr. Schwartz cited did not address the safety of the TVT-Secur or mini-slings in general. Rather, it addressed the safety and efficacy of full-length midurethral slings, such as the TVT and TVT-O. Dr. Schwartz failed to cite or consider[70] the Cochrane review that actually addresses the safety and efficacy of mini-slings,[71] "Single-incision sling operations for urinary incontinence in women," published in 2014. In it, the authors conclude that, "[o]verall results show that TVT-Secur is considerably inferior to retropubic and inside-out transobturator slings"; the "TVT-Secur is inferior to standard mid-urethral slings for the treatment of women with stress incontinence and has already been withdrawn from clinical use"; and "TVT-Secur is a specific type of mini-sling that has consistently been shown to provide poorer control of incontinence, along with higher rates of side effects, compared with standard mid-urethral slings. It has already been withdrawn from clinical use."[72]

Dr. Schwartz also failed to consider the following studies that conclude that the TVT-Secur is not effective (and in some instances not safe):

- Hota, LS, et al. TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures. Female Pelvic Med Reconstr Swg (2012;18: 41-45 (a RCT with a 54.8% failure rate and 19.1% exposure rate at 1 year).[73]

[69] Ex. O at 24:7-14; 37:2-6.
[70] Ex. O at 37:2-41:19.
[71] Nambiar A, Cody JD, Jeffery ST. Single-incision sling operations for urinary incontinence in women. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD008709. DOI: 10.1002/14651858.CD008709.pub2 (Ex. P).
[72] *Id.* at 3-4.
[73] Ex. Q (Hota).

- Cornu, JN, et al. Midterm Prospective Evaluation of TVT-Secur Reveals High Failure Rate. Eur Ural (2010) (results showed a 42% failure rate with the authors concluding that the TVT-Secure does not seem appropriate for first-line management of SUI).[74]

- Barber, MD, et al. Single - Incision Mini - Sling Compared With Tension - Free Vaginal Tape for the Treatment of Stress Urinary Incontinence. Obstet Gynecol 2012;119:328-37) (a RCT reporting a 44.2% failure rate).[75]

- Masata, J, et al. Randomized trial of a comparison of the efficacy of TVT-O and single-incision tape TVT SECUR systems in the treatment of stress urinary incontinent women—2-year follow-up. Int Urogynecol J (2012) 23:1403–1412 (a RCT reporting 31% failure rate and 12.5% reoperation rate).[76]

As this Court recognized in *Tyree v. Boston Scientific Corp.*, Case 2:12-cv-08633, Dkt. No. 444, p. 118 (*Daubert* Order), an expert's opinion is unreliable if he fails to account for contrary scientific evidence. Clearly, Dr. Schwartz has "selectively" chosen studies upon which to base his opinions and ignored others. The overwhelming weight of the published scientific literature establishes that the TVT-Secur is not effective and in some instances, not safe. Dr. Schwartz's opinions to the contrary are not based on scientific and medical literature, are unreliable, and should be excluded.

CONCLUSION

For the reasons above, this Court should grant Plaintiffs' Motion to Exclude Certain Opinions and Testimony of Brian N. Schwartz, M.D.

[74] Ex. R (Cornu).
[75] Ex. S (Barber).
[76] Ex. T (Masata).

This 21st day of April, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ P. Leigh O'Dell
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